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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,797	09/04/2003	Niel F. Starksen	016886-001300US	7101

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EXAMINER

ANDERSEN, MICHAEL T

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,797

Applicant(s)

STARKSEN, NIEL F. ✓

Examiner

M. Thomas Andersen

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 37-45, 51, 52 and 54-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35, 36, 46-50 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/16/06, 9/12/05, 11/22/04, 12/11/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

An election of species and restriction requirement was made in the Office action dated 6/15/2006. Examiner asserts that Applicant erroneously interpreted that election of species and restriction requirement as only a restriction requirement. Applicant elected Group II (claims 35-57) but did not elect a specific species. In a telephone call on August 16, 2006 with Mika Mayer the election of species requirement was explained and Applicant elected Species III (Figures 5A-8) without traverse. The claims readable thereon include claims 35-36, 46-50, and 53.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-34, 37-45, 51-52, and 54-60 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statements (IDS) received on 3/16/2006, 9/12/2005, 11/22/2004 and 12/11/2003 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

The disclosure is objected to because of the following minor informalities: page 8, line 4, "a" should read "an" ; page 9, line 13, "allowing" should read "allow" ; page 10, line 3, "deliver" should read "delivery" ; page 12, line 26, "hay" should read "may" ; page 13, line 14, "an" should read "a" ; page 14, line 2, "that" should read "than".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **35-36** are rejected under 35 U.S.C. 102(b) as being anticipated by **Taheri**, U.S. Patent No. **5,843,169**. Taheri discloses an apparatus and method for stapling using a balloon catheter.

Claim **35**: Figure 1a of Taheri discloses an elongate body 11 and a stabilizing member 15 at the distal end that is capable of being positioned under one or more leaflets of a valve of the heart to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart.

Claim **36**: The elongate member 11 can be said to comprise a rigid shaft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **46-50** and **53** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Taheri**, as applied to claim 35 above, in view of Brock et al., **US 2002/0087169**

(hereinafter "**Brock**"). Brock discloses a flexible instrument to deliver anchors using a balloon.

Claim 46: Taheri further discloses a semicircular housing (figure 5b) and an expandable balloon, but does not appear to disclose a plurality of *tethered* anchors disposed within the housing. Brock discloses in figures 36-37 a plurality of tethered anchors disposed within a circular housing. A semi-circular housing is considered an obvious variation of a circular housing, particularly in view of Brock. Brock and Taheri both involve inserting anchors into tissue using a balloon member. Further, a semi-circular housing would take up less space and would provide for a less-invasive surgery. It therefore would have been obvious to combine Taheri with Brock.

Claim 47: The hooks in Taheri or Brock can be considered curved hooks or straight barbed hooks.

Claims 48-49: Brock further discloses a pivot mandrel 409 around which the hooks pivot to engage annular tissue.

Claim 50: Brock further discloses an inflation actuator for inflating the expandable balloon; a release actuator for releasing the anchors from the housing; and a cinching actuator for cinching a tether coupled with the tethered anchors to reduce a diameter of the valve annulus. See e.g. paragraphs 0277 through 0283.

Claim 53: The hooks in Brock can be considered deployable mechanical support structures for constricting the valve annulus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

August 17, 2006



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER